NDA 09-218/S-097

DuPont Pharmaceuticals Company
Attention: James L. Gaskill, R.Ph.
Chestnut Run Plaza, MR2146
974 Centre Road
Wilmington, DE 19805

Dear Mr. Gaskill:

Please refer to your supplemental new drug application dated November 12, 1999, received November 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coumadin® (Warfarin Sodium Tablets, USP) Tablets and Coumadin® (Warfarin Sodium for Injection, USP) for Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following: in the PRECAUTIONS section, the "EXOGENOUS FACTORS" subsection (factors that may be responsible for INCREASED PT/INR response), the "Specific Drugs Reported" table, the addition of the drug names "celecoxib", "rofecoxib", and "capecitabine". Your submission stated January 4, 2000 as the implementation date for the changes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling submitted November 12, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Karen Oliver, Regulatory Health Project Manager, at (301) 827-7457.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research